

App. NO. 10/623,816

Amdt. dated August 26, 2004

Reply to Office action of May 26, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended). A non-toxic mucosal disinfectant composition of homogeneously mixed components for topical application in the nose, comprising:

an isopropyl alcohol component of at least 50% by weight;

a sesame oil component not exceeding 45% by weight;

a lemon oil or lemon balm component not exceeding 3% by weight, for supplementing and neutralizing a dehydrating effect of said alcohol; and

an aloe ~~or aloe-derivative~~ component not exceeding 10% by weight.

Claim 2 (original). The disinfectant composition according to claim 1, wherein said aloe component is aloin with emodin.

Claim 3 (currently amended). The disinfectant composition according to claim 1, wherein said sesame oil component is approximately 41% by weight, said lemon oil or lemon balm

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component is approximately 2% by weight, and said aloe ~~or aloe~~
derivative component is approximately 5% by weight.

Claim 4 (original). The disinfectant composition according to
claim 1, which further comprises approximately 0.5 to 2% by
weight grapefruit seed extract and approximately 0.5 to 2% by
weight chlorhexidine gluconate.

Claim 5 (original). The disinfectant composition according to
claim 1, wherein said isopropyl alcohol is at least 91% pure
isopropyl alcohol.

Claim 6 (original). The disinfectant composition according to
claim 1, which comprises the following formula, in % by
weight:

50% isopropyl alcohol
2% lemon oil
5% pure aloe gel 5-10% ok
2% chlorhexidine gluconate
41% sesame oil.

Claim 7 (original). The disinfectant composition according to
claim 1, which comprises the following formula, in % by
weight:

50% isopropyl alcohol (70-99%)

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41% sesame oil

5% aloin

2% lemon oil or lemon balm

1% grapefruit seed extract

1% chlorhexidine gluconate.

Claim 8 (original). The disinfectant composition according to claim 1, wherein said isopropyl alcohol component ranges from about 50 to 75% by weight, and said sesame oil component ranges from about 24.9% to 45% by weight.

Claim 9 (original). The disinfectant composition according to claim 1, wherein the composition has an effective treatment life of at least eight hours and a shelf life of at least two years.

Claim 10 (currently amended). A disinfectant composition for treatment of an infection for topical application in the human nose, comprising:

an isopropyl alcohol component of at least 50% by weight;

a sesame oil component not exceeding 45% by weight;

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a lemon oil or lemon balm component not exceeding 3% by weight, for supplementing and neutralizing a dehydrating effect of said alcohol; and

an aloe ~~or aloe derivative~~ component not exceeding 10% by weight.

Claim 11 (original). The disinfectant composition according to claim 10, wherein said aloe component is aloin with emodin.

Claim 12 (currently amended). The disinfectant composition according to claim 10, wherein said sesame oil component is approximately 41% by weight, said lemon oil or lemon balm component is approximately 2% by weight, and said aloe ~~or aloe derivative~~ component is approximately 5% by weight.

Claim 13 (original). The disinfectant composition according to claim 10, which further comprises approximately 0.5 to 2% by weight grapefruit seed extract and approximately 0.5 to 2% by weight chlorhexidine gluconate.

Claim 14 (original). The disinfectant composition according to claim 10, wherein said isopropyl alcohol is at least 91% pure isopropyl alcohol.

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Claim 15 (original). The disinfectant composition according to claim 10, wherein the composition has an effective treatment life of at least eight hours.

Claim 16 (currently amended). The disinfectant composition according to claim 10, which comprises the following formula, in % by weight:

50% isopropyl alcohol
2% lemon oil
5% pure aloe gel 5-10% ~~etc~~
2% chlorhexidine gluconate
41% sesame oil.

Claim 17 (original). The disinfectant composition according to claim 10, which comprises the following formula, in % by weight:

50% isopropyl alcohol (70-99%)
41% sesame oil
5% aloin
2% lemon oil or lemon balm
1% grapefruit seed extract
1% chlorhexidine gluconate.

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REMARKS/ARGUMENTS

Reconsideration of the application is requested.

Claims 1-17 remain in the application. Claims 1, 3, 10, 12, and 16 have been amended.

More specifically, the claims have been amended in response to the Examiner's objections detailed on page 2 of the Office action. While the amendments do indeed respond to a statutory rejection, namely a rejection under 35 U.S.C. § 112, second paragraph, the changes are of a cosmetic nature and they do not narrow the subject matter of the claims. To wit:

1) The alternative phrase "an aloe or aloe derivative component" now appears as "an aloe component." As pointed out by the Examiner, a derivative of aloe may, in a broad interpretation, encompass water. The intention of the limitation appearing in the claim, of course, was not to include such benign elements but instead to refer to the effective component derived from aloe. The current terminology "aloe component" includes aloe itself and the pertinent derivatives thereof. Importantly, the change is not a narrowing change.

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2) We have removed the term "ok" from the claims. This is a cosmetic change and it is in no way a narrowing amendment.

The specification and the claims meet the requirements of 35 U.S.C. § 112, first and second paragraphs. Should the Examiner find any further objectionable items, counsel would appreciate a telephone call during which the matter may be resolved.

We now turn to the art rejections, in which the claims have been rejected on two grounds, namely under an obviousness-type double-patenting theory and under a combination theory. Both of the rejections utilize the same combination of references, namely the older Viamonte patent 6,296,882 as modified by Danieli (U.S. 6,488,948), Shupe (U.S. 6,290,964), and Doi et al. (U.S. 5,908,865). Furthermore, the two rejections are based on the same underlying logic allegedly supporting the obviousness of the combination, and the Examiner underscores the allegation of obviousness by stating that the *prima facie* case has been made, "especially in the absence of evidence to the contrary."

In order to properly gauge the rejections, we must first review the state of the law. A *prima facie* case of obviousness can be made by combining various references. Case law also

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states that such a *prima facie* case of obviousness can be overcome by pointing out the criticality of certain limitations that are not recognized in the reference teaching(s). Such criticality can either be shown with corresponding support in the specification or it can be proved by later-submitted declarations and/or affidavits. See, In re Peterson, 65 USPQ2d 1379 (Fed. Cir. 2003). In the instant case, we have several statements in the specification and detailed information that provides for such indications of criticality of the narrow ranges in the composition. In fact, the very specification is built on various experiments - albeit with a limited number of testing subjects - which do indeed provide the necessary evidence that contradicts the Examiner's allegation of obviousness.

Before dealing with the evidence, however, we must address the combination of the references. That is, before the "secondary considerations" come into play under Graham v. John Deere Co., 383 US 1 (1966), the combination and the obviousness of the combination of the references must be reviewed. In this regard, it is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any

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suggestion or motivation in the prior art to make the selection made by the applicant". Interconnect Planning Corp. v. Feil, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". In re Bond, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined only if there is some suggestion or incentive to do so." ACS Hospital Systems, Inc. v. Montefiore Hospital et al., 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be 'clear and particular.'" Winner Int'l Royalty Corp. v. Wang, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Applicants believe that there is no "clear and particular" teaching or suggestion in any of the references towards the Examiner's combination. As such, the combination is artificial and based on hindsight, i.e., the references are combined by following the template provided by applicants' claims.

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In this case, any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the instant application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicants' structure as a template and selecting elements from references to fill the gaps. The references of record do not themselves provide the required teaching that would render the claimed combination obvious. In re Gorman, 18 USPQ2d 1885 (Fed. Cir. 1991).

Specifically with regard to the claims, the invention is indeed based on the prior Viamonte patent. The novel combination improves and enhances the earlier Viamonte teaching. There is provided a new solution with longer duration of efficacy, and broader germ-killing range. It is true that the most important active ingredient is still isopropyl alcohol. The primary active ingredient, however, is enhanced by various components, such as grapefruit seed extract, aloe, and chlorhexidine gluconate.

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There are two important issues, here. First, the components do not each separately work their effect but they combine in a synergistic manner to form a solution which is more effective and more useful than the components individually. Second, there is nothing in the art that would suggest the synergism, nor is there anything in the art that would suggest the combination itself.

The research provided by applicants further defined why several other components such as silver, petroleum jelly, tea tree oil, and the like, could not be used or should not be used for safety reasons and efficacy reasons. That is, we have not only evidence to support the synergistic effect of the combination but we also have contrary evidence that shows why certain elements should not be used and are thus eliminated from the claim.

The Examiner has found each of the additional components in the prior art as shown by the references. This is not, in and of itself, a defeat of patentability. On careful review of the references, we immediately find that the individual components are individually used and explained with regard to their efficacy, or they are provided in entirely different combinations. Nothing in the art suggests the synergistic effects of the claimed composition.

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Danieli '948 describes a water-based solution with chlorhexidine gluconate and cetramonium chloride as active ingredients. The reference does not mention combining solutions for the purpose of increasing the duration of activity on a mucosal or other surface.

Shupe et al. '964 describe a method where an active ingredient is isolated from an aloe leaf. The reference does not mention combining solutions for the purpose of increasing the duration of activity on a mucosal or other surface. Aloe only complements the solution according to the instant invention by adding antimicrobial efficacy, reduces alcohol smell and aids in tissue regeneration. Aloe is not the active ingredient in the instant invention.

Doi et al. '865 describe the stabilization of chlorhexidine gluconate for use with other chlorine or acid compounds. Chlorhexidine is not the active ingredient in the instant invention, it simply aids in increasing the efficacy of and also acts as a preservative. The reference also does not mention combining solutions for the purpose of increasing the duration of activity on a mucosal or other surface.

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In sum, none of the secondary references at all compare to the claimed invention, except that they deal with antimicrobial solutions and that they contain certain components of the claimed solution. The references fail to establish a *prima facie* case of obviousness.

In further summary, none of the references, whether taken alone or in any combination, either show or suggest the features of claim 1. Claim 1 is, therefore, believed to be patentable over the art and since all of the dependent claims are ultimately dependent on claim 1, they are believed to be patentable as well. Furthermore, even if the combination provided by the Examiner were acceptable as making out a *prima facie* case, the specific evidence contained in the specification clearly supports applicants' contention that the claimed invention is patentable.

In view of the foregoing, reconsideration and allowance of claims 1-17 are solicited.

If an extension of time for this paper is required, petition for extension is herewith made.

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Please charge any other fees which might be due with respect
to Sections 1.16 and 1.17 to the Deposit Account of Lerner and
Greenberg, P.A., No. 12-1099.

Respectfully submitted,



For Applicants

WERNER H. STEMER
REG. NO. 34,956

WHS:tk

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Lerner and Greenberg, P.A.
P.O. Box 2480
Hollywood, Florida 33022-2480
Tel.: (954) 925-1100
Fax: (954) 925-1101